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MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS, FL 33410

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CHERNYSHEV, OLGA N	
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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GEORGE JACKOWSKI and JOHN MARSHALL

Appeal 2007-3904
Application 09/991,796
Technology Center 1600

Decided: December 21, 2007

Before DEMETRA J. MILLS, LORA M. GREEN, NANCY J. LINCK, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal[1] under 35 U.S.C. § 134 from the Examiner's final rejection of claim 1. We have jurisdiction under 35 U.S.C. § 6(b). The claim reads as follows:

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[1] This Appeal is related to Appeal Nos. 2007-3735, USSN 09/993,344, and 2007-3905, USSN 09/991,799, which are decided concurrently with this Appeal.

1. An isolated biopolymer marker which evidences a link to Type II diabetes selected from the group consisting of SEQ ID NO: 1 and SEQ ID NO:4.

We reverse the rejections of record, but raise other issues that the Examiner should consider upon return of the administrative file.

BACKGROUND

According to the Specification:

> This invention relates to the field of characterizing the existence of a disease state; particularly to the utilization of mass spectrometry to elucidate particular biopolymer markers indicative or predictive of a particular disease state, and most particularly to specific biopolymer markers whose up-regulation, down-regulation, or relative presence in disease vs. normal states has been determined to be useful in disease state assessment and therapeutic target recognition, development and validation.

(Specification 1.)

Samples are collected from an individual, at one point in time or at different points in time (Specification 31), and are resolved using polyacrylamide gel electrophoresis (*id.* at 38). The protein bands are cut from the gel, and are cleaved into fragments using proteolytic enzymes (*id.*). The peptides are collected and purified by reversed phase chromatography, and then subject to identification by mass spectrometry (Specification 38-39).

The Specification teaches further:

> The human genome contains the genes that encode all proteins. The proteolytic cut sites within all these proteins can be predicted from the translated amino acid sequence. The mass of the peptides that result from the predicting cut sites can

> be calculated. Similarly, the fragmentation pattern from each hypothetical peptide can be predicted. Thus, we can conceptually digest the proteins within the human proteome and fragment them.
>
> When a peptide has been "sequenced" it is understood that the peptide fragment has been purified by one of the methods above, i.e. Time of flight (TOF) or by chromatography, before fragmenting it with gas to produce the peptide fragments. The original peptide mass and fragmentation pattern obtained is then fit to those from the theoretical digestion and fragmentation of the genome. The peptide that best matches the theoretical peptides and fragments and is biologically possible, i.e. a potential human blood-borne protein, is thus identified. It is possible to identify plural targets in this fashion.

(Specification 39-40.)

As to the peptide of SEQ ID NOs:1 and 4, the Specification teaches:

> As a result of these procedures, the disease specific markers namely Fibronectin Precursors having a molecular weight of about 1629.94 daltons and a sequence of SEQ ID NO: 1, a molecular weight of about 1927.0442 daltons and a sequence of SEQ ID NO: 2, a molecular weight of about 2127 daltons and a sequence of SEQ ID NO: 3, a molecular weight of about 1629.87 daltons and a sequence of SEQ ID NO: 4, a molecular weight of about 1913.08 daltons and a sequence of SEQ ID NO: 5, and a molecular weight of about1682.96 daltons having a sequence of SEQ ID NO: 6 related to Type I1 diabetes were found.

(Specification 46-47, as amended September 22, 2003.)

DISCUSSION

Claim 1 stands rejected under 35 U.S.C. § 101 "because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility or a well established utility." (Answer 3.)

The rejection of the peptides of claim 1 is predicated on the argument that the Specification does not disclose whether the fragments are "present, not present or present at different levels in samples obtained from Type II diabetes patients" (*id.* at 5), and thus the Specification has not established the utility of the peptides as biomarkers for Type II diabetes.

As acknowledged by the Examiner, the Specification teaches that the peptides of SEQ ID NOs:1 and 4 are fragments of fibronectin precursors (*id.* at 4). Thus, if we take a step back and look at the subject matter of the claim, at bottom, claim 1 is limited to peptide fragments of a known protein, fibronectin precursor. Increases in fibronectin immunoreactivity have been observed in capillary basement membranes in rats with spontaneous diabetes as compared with nondiabetic age-matched controls (Grant,[2] p. 1338, second column) Grant also teaches that in diabetes, excess fibronectin is generated and available for degradation (abstract).

Thus, peptide fragments derived from fibronectin precursor would have the well established utility as antigens for the generation of antibodies which can be used to localize or assay for the protein. We note in addition that the Specification also discloses that antibodies may be raised to the markers disclosed by the invention (Specification 49-54). Thus, as we conclude that the peptides of SEQ ID NOs:1 and 4 would have the well established utility of generating antibodies specific for fibronectin precursor, we are compelled to reverse the rejection.

The Examiner also rejected claim 1 under 35 U.S.C. § 112, first paragraph, on the grounds that "since the claimed invention is not supported by either a clear asserted utility or a well established utility . . . one skilled in

[2] Grant et al., "Fibronectin Fragments Modulate Human Retinal Capillary Cell Proliferation and Migration," *Diabetes*, Vol. 47, pp. 1335-1340 (1998).

the art clearly would not know how to use the claimed invention." (Answer 8.) This rejection is also reversed for the reasons set forth above.

OTHER ISSUES

Upon return of the administrative file, the Examiner should reevaluate the patentability of the claim in view of the prior art.

As acknowledged in the Specification, SEQ ID NOs:1 and 4 are fragments of fibronectin precursor (Specification 46). Moreover, the Specification teaches that specific sequences were determined as a fit to those from the theoretical digestion and fragmentation of the genome. Thus, SEQ ID NOs:1 and 4 are trypsin fragments of a known protein sequence.

Given the method of sequencing laid out in the Specification and discussed above, the sequence of the peptide of SEQ ID NOs:1 and 4 must be derived from a known sequence of fibronectin precursor.

CONCLUSION

In summary, we reverse the rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, but raise other issues as to the patentability of claim 1 that the Examiner may wish to address upon receipt of the administrative file.

REVERSED

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MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS FL 33410